

**2007 HIV/AIDS Implementers Meeting: State of the Art:  
Rolling Out Opt-Out and Other New Approaches  
PEPFAR, The Global Fund to Fight AIDS, Tuberculosis  
And Malaria, UNAIDS, UNICEF, The World Bank, WHO, GNP+  
June 16, 2007**

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[START RECORDING]

**MALE SPEAKER:** [Inaudible] better way, better approaches in HIV testing. [Inaudible] a great pleasure to introduce [inaudible] HIV, the U.S. government in 2004. At that time, Kevin was county director for CDC program [inaudible]. It was a time of great experience, great planning and [inaudible] and I feel privileged to be in Kevin's team which I thought was the winning team and makes me feel [inaudible]. Kevin [inaudible] WHO as director of the WHO [inaudible]. He is an HIV/AIDS expert and Kevin is a renowned physician [inaudible] HIV testing and he is going to take us through innovative approaches to HIV testing [inaudible] After that, we will have [inaudible] then after than we will attempt questions [inaudible]. He came back in 2001 as a director of CDC [inaudible] from 2000 to 2006 when he took up his title from WHO. I feel very [inaudible]. [Applause]

**KEVIN DECOCK, M.D.:** Thank you very much for that kind introduction. Colleagues, comrades, friends, I very sincerely thank the organizers [inaudible] speak on this subject of HIV testing and I congratulate everybody and thank everyone involved with putting this whole [inaudible] together. Let me start by first acknowledging the contributions of [inaudible] persons at the World Health Organization, UNAIDS, CDC, UNICEF, elsewhere, this is [inaudible] on the slide [inaudible] over

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the past years concerning this important topic. In our own group relating to recent guidelines I'll be talking about to some extent, particularly want to highlight the contributions of Donna Higgins, [inaudible] and Ian Grub who were central to coordinating with many others the recently released guidance. My talk is not their responsibility. It may have some elements of that famous clinician who was often wrong but never in doubt.

I'll skim over the history of HIV testing and review current testing coverage and its consequences. I will comment on classification of testing and discuss HIV testing in health care settings, the subject of that recent guidance, and I will examine some different approaches to HIV testing outside of health care settings and close with some comments about some current debates and some prospects for the future.

The first serologic test for HIV was licensed in 1985. Fresher to introduce HIV testing, it was driven by concerns about the safety of the blood supply. To avoid persons seeking knowledge of their HIV status through donating blood, voluntary counseling and testing was introduced and in the United States it rapidly became an important part of the HIV/AIDS prevention response. Concepts of the three C's, consent, counseling, and confidentiality dates back to that time. In the early 1990's the ACTG-076 study showing a two-thirds reduction in perinatal

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transmission of HIV from mothers to their infants with the zidovudine regimen challenged approaches to HIV testing and led at least in the industrialized world to changes in practice and greatly increased antenatal testing. The advent of combination therapy in 1996 further enhanced this but practice in the developing world lagged behind. A document from the World Health Organization in 2003 entitled "The Right to Know" endorsed the concept of so-called opt-out testing and was followed in 2004 by a joint UNAIDS WHO policy statement that recognized different reasons for testing, reinforced some basic principles, and was permissive of different approaches in different settings. Despite progress in individual countries, the policy statement failed really to gain traction and it was handicapped by lack of adequate follow-up and some ambiguity in the text. At the end of May of this year on the 30<sup>th</sup> of May, WHO and UNAIDS issued new detailed guidance on provider initiated HIV testing and counseling and in the United States of course CDC have revised guidelines for the U.S. on this subject in September of last year. Globally, knowledge of HIV status is low. In 12 African countries surveyed, only 10% of women and 12% of men overall had been tested for HIV and received their results. Considering persons who are HIV positive, only about 20% of persons in these African countries are aware of their infection status. Only about 10% of

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pregnant women in all low and middle income countries are accessing HIV testing; the median estimate for the ten countries on this slide, the ten countries that contribute two-thirds of the world's HIV positive pregnancies, being less than 20%. Only 14% of the total estimated patients with HIV associated tuberculosis received an HIV test in 2006; 13% for African patients who contribute over three-quarters of HIV positive TB. So, to reiterate, 80% of persons living with HIV in Africa are not aware of that, only 10-12% of persons overall have ever been tested for HIV and received their results, and we know that HIV infected persons flow through health care settings but often even mostly do not get tested for HIV and under these circumstances one could ask what does it mean to speak of universal access?

The consequences of lack of knowledge of serostatus are measurable in failed prevention disease and death. In 2006, an additional 700,000 persons initiating ART brought the total in low and middle income countries to over 2 million; 1.3 million in Africa in pink or brown, light brown on this slide, but that coverage, 1.3 million in Africa, was only 28% which also is the global estimate of ART coverage of those in need. This means that there are more than 4 million persons world wide shown in dark brown in need of access to therapy. Now, lack of testing is one, though obviously not the only barrier. Children, along

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with injecting drug users, are especially under served and diagnosis of children severely lags behind. This slide shows the proportion of ART recipients in different regions who are children. Children make up about 15% of the world's AIDS deaths. This very low rate of HIV testing of tuberculosis patients, this slide shown previously, converts into preventable deaths since without ART the mortality in HIV infected TB patients is approximately 25% at two years following diagnosis of tuberculosis despite TB therapy. And all is not well in the industrialized world either. In the United Kingdom, approximately one-third of all newly diagnosed persons shown here in green had a CD4 count below 200 cells per cubic millimeter around the time of their first HIV diagnosis and the proportion in male heterosexuals in the U.K. who were mostly African is almost one half.

Observational cohort studies comparing treatment outcomes in the industrialized and developing worlds have shown a substantially increased risk for early death among patients in the south, shown in this slide, as greatly increased hazard ratios over four in the first month of treatment; 73% of these deaths were in persons whose CD4 counts at treatment initiation were below 100 cells per cubic millimeter; 38% of deaths occurred in the first month, 80% in the first four months. Delayed HIV diagnosis clearly is bad for your health. Finally,

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prevention of mother to child transmission, in this well known cascade showing drop off for the different steps involved in delivering PMTCT, the biggest single gap remains the testing of women attending antenatal care. HIV testing alone of course does not guarantee appropriate services but without HIV testing, any specific service delivery is impossible.

The traditional model of voluntary counseling and testing is not appropriate to all settings. These four vignettes illustrate the differing requirements of people at different life stages. Persons wishing to know their HIV status for life planning may be well served by this traditional VCT center at the top left of this slide which cannot however assure PMTCT services to the mothers of these infants or appropriate follow up for the infants' own diagnosis and care. This young woman on the top right in an STD clinic, someone's daughter and sister, needs investigation and advice about a range of sexually transmitted infections including HIV. Knowledge of HIV status will determine the emergency management of this severely ill man whose chest x-ray is shown at the bottom of this slide who might have Pneumocystis pneumonia, tuberculosis, or no HIV associated illness at all.

Kenya's far sighted guidelines on HIV testing in clinical settings published in late 2004 divided HIV testing into a number of different categories listed here. Terminology

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bedevils this whole discussion and words like routine easily are misinterpreted, routine often misinterpreted as mandatory. For simplicity, WHO and UNAIDS have gone for lumping rather than splitting and we have broadly divided HIV testing into clients initiated where the individual actively seeks out testing and provider initiated where a health worker recommends testing to patients.

A third category is mandatory testing which UNAIDS and WHO advise has little public health role outside of testing of blood, organ and semen donors. Because of confusion and gender, we are also avoiding as far as possible the terms opt-in and opt-out, although I confess I will use them once or twice in the comments that follow. I am reminded of Humpty Dumpty who said that he used the term to mean exactly what he meant at that time.

On May 30<sup>th</sup> of this year, WHO and UNAIDS released this document, "Guidance on HIV Testing and Counseling in Health Facilities" to respond to requests from countries for guidance, to provide advice in the context of often confused and sometimes suboptimal practice internationally and to hopefully stimulate increased HIV testing in appropriate clinical setting. It results from extensive consultation including a web based public comment period and we are deeply grateful to all those who took time to advise us.

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Life is hard at WHO. Inside every WHO bureaucrat is a health radical trying to get out. [Laughter] WHO has to walk a fine line between pressure from often opposing perspectives and in addition global guidance has to address all epidemic types and diverse sociocultural public health context indicated by the cartoon on the right for which there is no one size fits all solution.

The guidance states that everywhere in the world, everywhere in the world, HIV testing and counseling should be recommended to patients whose clinical presentation could result from underlying HIV infection including patients with tuberculosis. For all children born to HIV infected mothers and to males seeking circumcision as an HIV prevention strategy, this recommendation for testing should ordinarily lead to the test being performed unless the patient declines. Now what about patients consulting for reasons not obviously related to HIV infection? The clinician here is saying off hand I would say you are suffering from an arrow through your head but just to play it safe I am ordering a bunch of tests.

The WHO and UNAIDS guidance advises that in generalized HIV epidemics as in the context of Sub Sahara and Africa, HIV testing should be recommended to all persons attending health care setting irrespective of the reason for consulting.

Implementation of this recommendation can be, must be, phased

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in progressively with prioritization of settings such as medical clinics and wards, maternal health services, STI clinics, etc. The guidance has specific recommendations also for concentrated epidemics, recommending more targeted HIV testing which time precludes me from discussing further right now. The guidance also, very importantly, considers testing in children and also for adolescents, again which I won't go into for lack of time. I do urge you to get the document off the website or write to us if you can't get it, it's a long document. I think it is good. I am certainly it is good enough. It is long but if you can't read the whole document, read the executive summary and we do think, we do hope that it is a significant contribution. Now, the recommendation for HIV testing should not be coercive or construed as mandatory. HIV testing should not be conducted against patients' will, without their knowledge, without information, without counseling around the results or without linkage to appropriate services. Decisions about testing should always as with any clinical interaction, should always be in the best interests of the individual patient and inclusiveness, consultation and careful adaptation to local conditions including the available resources and local socio-legal protections are advised, and monitoring of implementation can lead to adjustments in response to documented problems. Some countries are already

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ahead, reminding us of the Chinese maxim that the man who says that something cannot be done should get out of the way of the man who is already doing it. At Zambia's teaching hospital in Lusaka, provider initiated HIV testing is already being undertaken including among hospitalized children with the consequent provision of cotrimoxazole and ART to those in need because I was given this slide by some colleagues from CDC, I have not changed the use of the terms routine because I said earlier it is one that in our guidance we have avoided because of confusion.

The country with the most experience is probably Botswana which initiated more generalized testing in health facilities following a presidential decree over three years ago. Botswana's minister of health has spoken forcefully about the overwhelmingly positive impact of the revised testing practice in her country and the impact on treatment uptake and in her important opinion reduction in levels of stigma. Combined with these global discussions, the release in September 2006 of revised guidelines in the United States contributed to ongoing review in some European countries such as France and the United Kingdom about the appropriateness of their current testing practices in clinical settings. Now, conditions may never be completely right to implement provider initiated HIV testing and as with introduction of ART programs

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themselves, at some stage as the Nike ad says, one just has to go ahead and do it, just do it. Please read the WHO UNAIDS guidance, take all possible precautions and preparatory measures but if we are to make progress we need to move. I believe that the guidance offers balance and opportunity to expand management of HIV in health care settings in places where it is needed most.

Now let me reiterate that WHO and UNAIDS endorse scale-up of both clients initiated and provider initiated testing and counseling. This paper in PLOS Medicine on the left by David Holtgrave pits one against the other as if it's a choice of either or and I have heard several activists do that also. For example, recently on a trip in Asia, this is a false dichotomy. It should not be either or and the either or would be as our colleague Ron Valdisary writes in an accompanying commentary an either or would be both bad clinical medicine and bad public health. These approaches are not mutually exclusive. They should be mutually reinforcing.

Diverse approaches exist to scale up clients' initiated testing and counseling. Now, the alphabetic approach to HIV prevention has now been carved into the lexicon but I think it could benefit from some expansion. Seek and refer to male circumcision as well as clean needles and syringes. D stands for diagnosis, i.e., HIV testing and E stands for everything

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else through to Z. But testing has critical prevention potential including very importantly the prevention services for HIV infected persons. Almost everywhere that HIV counseling and testing has been scaled up, there has been initial suspicion and uncertainty shown by these reports some years ago from the Kenyan media. Some of the major requirements for introducing and scaling up VCT and some of these elements apply to provider initiated testing as well are listed here. Community advocacy, financing, normative guidance, quality assurance, protocol straining, personnel including new cadres of staff, perhaps through task shifting, laboratory aspects, commodities management, monitoring and evaluation, introduction of rapid tests has of course been especially important along with the empowerment of lay counselors or others to perform these tests other non-laboratory personnel to perform these tests under appropriate supervision.

The only limits to the diversity of models for delivering client initiated testing and counseling or sites where it can be done is our imagination. The diversity of situations at risk taking suggests that we are far from exhausting innovation. Most VCT to date has been through fixed site facilities either based in health care settings or stand alone centers. VCT has been delivered in community based

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facilities such as church halls, through occupational health settings including in the military and uniform services, through mobile services, home based delivery, or targeted services to specific groups, and also services targeted to families of HIV infected persons participating in treatment initiatives.

Scale up in many countries has been quite spectacular, shown on this slide by the increased number of people tested as well as the increased number of officially registered VCT centers in Kenya. Elizabeth Moram kindly gave me this slide and we heard Rwandan data from His Excellency the President this morning. In Kenya, mobile services have been introduced with civil society involvement, service delivery use specially modified vehicles, truck based containers, tents, and even in more remote areas deployment of VCT counselors by bicycle or even by camel. Note the camel delivering integrated VCT and family planning. [Laughter] A model of best practice! Tell PEPFAR you need to buy camels!

Mobile VCT has been especially suited to rural areas achieving high uptake, detection of many unrecognized infections and appreciated by communities because of the anonymity of the itinerant VCT staff. A more active form of service provision has been home based VCT, that is VCT shown here, offered to a whole district in Uganda, linked to

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provision of a basic HIV care package including specific advice for discordant couples and ART referral and adherence support. I am grateful to Becky Bunnell for these slides. Almost 200,000 persons were reached. Acceptance was over 95%, coverage over 80%, the end result being 8,000 people receiving necessary services. A targeted approach may also be useful. In a paper in *JAIDS* last year [Inaudible] described household VCT targeted at the families of indexed patients identified through an ART program. Over 2,000 family members of 730 indexed patients were approached in their homes. Acceptance of VCT was 99% and overall HIV prevalence in family members was 7.5%, a remarkably high prevalence, 9.5%, was found in children aged less than five years and prevalence was very high in adults and spouses, 37% and 57% respectively. As described previously in different settings, almost one half of partners, of HIV infected indexed patients, were discordantly HIV negative. These few examples of testing and counseling outside of health care settings show an increase in the intensity of effort at finding HIV infected persons. Traditional VCT being analogous to passive case finding, home based VCT to slightly intensified case finding, family outreach, somewhat analogous to active case finding in other diseases. Relevant issues in addition to numbers of unrecognized HIV infections detected through different approaches are cost effectiveness and staging

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in those newly diagnosed with HIV. Again, Dr. Becky Bunnell told me that for persons diagnosed through door to door VCT, the median CD4 count was over 400 per cubic millimeter in contrast with family based VCT around indexed patients, 40% of persons newly diagnosed with HIV were clinically eligible for ART themselves. Door to door VCT may also offer the lowest cost for the client completing testing and counseling. These various initiatives are creative, imaginative, effective, but what is inadequately discussed is what the end game should be. What constitutes success? What percentage of the population should know their serostatus and at what stage of disease should they learn it? Seventy-five percent of infected persons knowing their status in the United States, far above the 20% estimated in Africa was deemed inadequate and led to those CDC revised guidelines. The situation in the United States with that coverage of 75% does not prevent substantial numbers of persons learning their serostatus for the first time because of an AIDS defining illness and it was one of the major stimuli to those revisions, so 90% detection of HIV for example would have a mean CD4 count of 100 could really not be considered success. In this *Lancet* paper four years ago, Dorothy [inaudible], Elizabeth [inaudible] and I raised the question of whether in African high burden settings universal knowledge of serostatus should not be a stated goal. Knowledge of serostatus would

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then become central to HIV prevention and care, the messages being, get tested. Disclose your HIV status to your partner before you have sex; never have unprotected sex with a partner positive or unknown HIV status; if HIV positive, abstain or always use condoms. If HIV positive, seek treatment, care and support. Learn your HIV status if pregnant and seek appropriate interventions.

Now, except for the testing of blood, organ and semen donors, WHO and UNAIDS do not support mandatory testing as a public health strategy and that is a philosophy going back to the beginning of the epidemic. Despite this, practice and debate in certain quarters have reduced emphasis on the voluntary aspects of testing. In China, routine testing shown on the left of the slide, has been introduced for groups at risk with probably limited emphasis on the right to decline and HIV testing for surveillance purposes has been linked to interventions for individuals, thus identified as HIV infected. This paper in *Science* a year ago defended the Chinese approach on the basis of the greatly increased diagnoses made, the increased provision of services to infected persons compared to what was previously achieved through traditional VCT and the stated public health responsibility of keeping HIV uninfected persons negative. In South Africa, there has been intense debate following the recent publication of this article on the

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right of the slide in the *South African Sunday Times* and subsequent discussion at the recent National AIDS Conference about mandatory testing. Quote: The existing voluntary system protects no one, simply deferring individuals' facing of the truth to when they are already ill and the effectiveness of treatment compromised, rights [Inaudible] a prominent South African HIV clinician. Quote: South Africa needs a new HIV testing policy. The current model, voluntary counseling and testing, which relies on initiation by the client, is well intentioned but deeply flawed. It is failing and has failed throughout the world. End quote.

At that South African conference, Venter expressed these comments and was met by the assembled activists and AIDS workers in a room with probably close to as many people as here tonight. He was met not with cat calls or tomatoes which I was expecting but with a mixture of quiet disagreement and some vocal support. Important guidance concerning restrictive public health measures is provided by the Syracuser principles which I think are extremely important. Public health can be restrictive of civil liberties or human rights. Witness the invoking last week, for the first time in 40 years of the United States federal quarantine authority in the case of a traveller with extensively drug resistant tuberculosis. The Syracuser principles require that restrictive or intrusive

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interventions should be sanctioned by law, aimed at a legitimate public health goal, be strictly necessary, be no more intrusive or restrictive than necessary, and be non discriminatory in application. In my opinion, we are far, very far, from having exhausted all less restricted avenues to increasing testing and in my opinion there seems no justification for mandatory testing. Nonetheless, I see a warning to us all in these Chinese and South African discussions that we in the main stream need to do better or more extreme voices will fill the vacuum. I am personally troubled and perplexed by the hypothetical question, what will we do if the prevalence of HIV in young adults, in Washington D.C., in Atlanta, in Paris, were 30%? Interventions to assure regular testing and universal knowledge of HIV status combined with universal provision of services might not be coercive but they would be intense.

In closing, AIDS repeatedly presents golden opportunities that are skillfully disguised as apparently irresolvable problems. The human suffering from HIV is unrivaled. Over 20 million Africans have likely died of AIDS, mostly unnamed, undiagnosed, uncounted, probably more actually than were taken in the slave trade. Your work illustrates that interventions are effective and can be implemented to scale. Thirteen years ago in this country, 800,000 people died in 100

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days and the United Nations general in charge of peace keeping wrote in his haunting autobiography, *Shake Hands with the Devil*, of international proclivity on the basis of respect of sovereignty and country rights while Rwanda was burning. How will history judge our approach to AIDS, our use of available tools including HIV testing for prevention and treatment? Have we been passive? Have we got it right? Are we doing too much? Early experience in the 1980's and visionary leadership at that time defined the response that since then has been buffeted by the rapidity and the extent of technical advances, epidemiologic trends and sociopolitical change. HIV testing and treatment access which is central to your work are emblematic of this evolution, questioning long standing dogma and assumptions in global health concerning what can and cannot be implemented. The WHO logo on the slide represents public health and health workers everywhere whose duty is to speak up for the human rights to life and health, adherent to medical ethics, routed in social justice, committed to human decency. The activists via it in AIDS, voter registration or whatever, taught us that rights are rarely given, often they must be taken. We in health must strive for balance in these debates including about testing but we will be held accountable for our choices and their consequences. We will be held accountable and we will not find rest or solace in what Martin Luther King

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described as the greatest tragedy of this generation that history will record, the appalling silence of the good people. Thank you. [Applause]

**MALE SPEAKER:** Thank you very much Kevin for a very provocative discussion, a presentation on HIV testing. I believe we have reached that time when we want to have some feedback from you as the audience. I am sure this huge turnout is not to come and see me. So, for those people who have come with questions, the ladies with the mic will you please stand in a place and then the people with questions can move to the ladies with the mic. As the people are preparing to ask questions, we are inviting Elizabeth Maram to join us in the panel as well as [inaudible] from WHO. Could you join us? If you could join us as the people are preparing to ask questions, the lady standing in the middle of the room, please if you have questions or comments, move to the, raise your hand or move to where the lady is. Are there any questions? There is a question up here. As you are trying to move to the mics, there is a housekeeping note I have been given here. The PEPFAR points of contact, please meet at [inaudible] in front of the postal tents tomorrow morning at 7:30. That is for the PEPFAR points of contact. I am sure you know yourselves, please meet at [inaudible] in front of the postal tents outside here tomorrow morning at 7:30. Questions, please.

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**LISA NELSON:** Yes, this is Lisa Nelson from the CDC in Mozambique and first of all I would just really like to thank you for your leadership on this issue. I think it is really critical for all of us to think about what you have said. My question relates to children where I think that the traditional client initiated services have not really well served the needs of children but I think even in the provider initiated setting where the testing is more complicated and the venues are quite different I would be curious about your thoughts about how we should be addressing their needs?

**KEVIN DECOCK, M.D.:** First, let me emphasize that although we are pleased with that guidance that I talked about, it is actually quite specific and narrow because it relates purely to health care settings and there are huge issues about testing outside of health care settings of children and adolescents which have not been well addressed and we need to do that. The guidance does cover as best as we could the issues in children. Obviously, socially it is much more difficult because you are indirectly testing the mother and there is the technological issue of diagnosing HIV in infants and there is the whole issue of disclosure to children which is a very difficult area but most of these issues are covered in the guidance and again it, you know, it is experience like yours and learning by doing that will improve the practice from

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these rather theoretical considerations but we have left children behind and we have to address it.

**ARLENE BURK:** Arlene Burk from USG Team, Zimbabwe, thank you very much for a very good presentation. My question relates to home testing. Do you think there is a role for home testing so that people can test themselves and get to know their status? The technology is here at the moment, the kits are getting better. Thank you.

**KEVIN DECOCK, M.D.:** I'm going to share some of these questions with my colleagues. I am going to pass that one on. Actually I meant to mention home testing and I forgot.

**ELIZABETH MARAM:** I think that it is going to be happening whether or not we endorse it. It is already happening to some extent. Health workers we know take rapid test kits home and test themselves and sometimes family members. I have long thought that we should perhaps at least do some pilot studies of the impact of self testing. There is a small study going on in Kenya of allowing in a study having health workers have the option of self testing at home so we will be looking for the results from that study but I think we have probably, as Kevin said, the man who says it can't be done needs to get out of the way of those who are already doing it and I think that people are doing it, will do it more, and that we probably should get involved so we can guide the process,

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make sure that package inserts are appropriate, give the right information, and perhaps do some public campaigns to prevent coercive testing at home but I think it is going to happen and we probably need to get more involved.

**MALE SPEAKER:** Good evening. I am a program manager of Indian National AIDS Control Program in the state of [inaudible], I have a concern and apprehension about the provider initiated testing and counseling. The first is about the very burden of the intervention, PITC, so [inaudible] presidents over counseling and the apprehension is like with PIT being implemented in a country like Indian where more than 99% of the adult population is not infected, won't there be a revival of pre-surgical and pre-procedural testing which we have tried to control with a lot of difficulties?

**MALE SPEAKER:** We just had a consultation on this very topic with our two regional offices in Asia and Kevin didn't have time to expand on what the recommendations are for low and concentrated epidemics but for low and concentrated epidemics is that all people presenting to the health service with symptoms of HIV infection should be tested with all the safeguards that are in the guidelines of provider initiated testing. The children who present with conditions that could be due to HIV infection should be tested and that beyond that, in those settings an assessment would need to be made where

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else provider initiated testing should be offered and epidemics and concentrated epidemics, it might make a lot of sense to offer it to pregnant women. It might make a lot of sense to offer it to SGI's but we have deferred this decision to national level discussions with the strong bias that at least in those two services that it should be offered whether beyond that, you would start offering it to populations at high risk of HIV infection who would not have sufficient safe guards for the human guides and against discrimination I think is a significant question. I think we would understand that people would be more conservative in those circumstances.

**FEMALE SPEAKER:** Thank you Dr. DeCock for your presentation. I am back here. I always learn something from your presentation and I am never disappointed so thank you! Can you provide us some guidance on any updates or activities that would help us understand the current thinking about same visit testing with, particularly with oral rapid testing and also for patients who are positive and given results back at the same visit?

**KEVIN DECOCK, M.D.:** Well, I think, I mean I just mentioned one sentence about rapid testing but I think there, I mean they are one of the key advances that have on a practical level moved the whole field forward. There are several issues in your question, the use of rapid tests, the issue of

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supplemental or confirmatory testing and how you do that and the use of oral testing. You know, there is plenty of data to show that confirmatory testing or supplemental testing of initially positive results does not require western blot. It can be done using other tests, rapid tests or ELISA tests, provided they use a different preparation. The performance of that algorithm is excellent and yet there are a number of countries including the United States where this is not allowed or not done or not introduced and for the life of me I don't understand it. But, those are the sorts of regulatory issues on a local level that need to be changed. One of the great advantages in our experience in the last few years in Kenya certainly was an advantage that rapid tests bring is that they get rid of a whole series of requirements of logistics, accurate record keeping, communication of results across hospitals and stuff, which doesn't work well in resource poor settings and a blood safety study some years ago demonstrated an extraordinary rate of incorrect labeling of transfused blood simply because of clerical errors so the fact that rapid tests could be done on the spot in front of the client by the patients or near the patient in the hospital it's on I think is a very important advance. The guidance actually allows a variety of approaches. It is not prescriptive but it does emphasize the utility of rapid testing. We made a bit of a

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mistake on oral testing or we miswrote when we said that WHO had not approved oral testing. We then got it in the neck from a company and actually that's not true, oral tests have been approved but again it is up to local people, nationals to figure out what tests are available in their setting and what is the performance of those tests.

**ELIZABETH MARAM:** If I could add to that, actually oral testing has been done some in the U.S. Last year on national testing day, June 27<sup>th</sup>, something like 80,000 people in Washington, D.C. were tested with an oral test and those who were positive were told to go to their health care worker for additional tests for confirmation. They were told the ones that were found to be positive were told that their results were provisional, that they were probably positive and that they should again go to their health care worker, both for confirmatory testing and for follow up on care and all the reports that I have read of that event in the U.S., there were no adverse outcomes using an oral test. I think again it is a technology that is going to be used more and more. It is being used in some countries and clients and patients like it, anything that avoids a painful finger prick or venipuncture is preferable to people and I personally think we probably should be at least pilot testing the use of an oral test and then try different methodologies for confirmation but certainly if we

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are responsive to what the people would like, we would be using oral tests more.

**MALE SPEAKER:** Dr. DeCock, I worked on the licensing of the original HIV test in 1985 so it is an issue I have been attached to for quite some time and I want to thank you for your presentation. There was absolutely nothing in the presentation that I disagreed with. What concerns me is what you didn't talk about. I don't believe that the challenges of stigma and discrimination are a reason to not move forward and be more aggressive about testing but to fail to mention those challenges in your presentation and to offer some guidance about how we address those challenges as we try to improve testing rates is concerning to me.

**KEVIN DECOCK, M.D.:** Thank you for raising that. We are certainly, I am not and my colleagues are certainly not dismissive of the important issues you raise but I do have to be impressed with practical experience I have been associated with which is in different countries what we have seen is that once we get over, once this is introduced and there is more familiarity with it, some of these obstacles go away. Now, a few weeks ago at the World Health Assembly in Geneva, I heard the Botswana Minister of Health speaking for 10-15 minutes about the impact of the presidential decree in her country and just how this changed everything and led to hugely increased

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treatment uptake and her words, not mine, a tremendous reduction in stigma. Now, I always emphasize when talking about stigma there is a difference between stigma and discrimination. Discrimination we can devise structural interventions to try and reduce. We can have laws, regulations, etc. Stigma is a much more, it's a very human issue. It is not something to be proud of but it is very human and I don't, you say I didn't give any advice about how to reduce it, I think familiarity reduces it in my experience but I am not sure we are ever going to completely get rid of it because we see stigma with lots of other diseases. I mean, a woman who has a mastectomy for cancer of the breast is, feels very stigmatized, and then you know, one thing I try to get across is you make your choices and you take ownership of the consequences. The natural history of HIV is very well understood and is extremely unforgiving and the diagnosis of HIV disease will declare itself, so to some extent it's a question of time and you decide whether it's better to be restrictive in testing or more expansive as I have argued for. You take credit for the stigma and discrimination you avoid and you take ownership of the preventable disease and death, and that is how it is and it's not by choice. That is how it is.

**DENNIS:** Thank you. [Inaudible] from [inaudible],  
Tanzania. Just wanted to comment on the question of testing in

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children. I think if the person emphasized the benefits the child would get and especially the younger child that is tested for antibodies for being exposed to HIV, if the policy laid a lot of emphasis on the benefits the child would get by being tested for antibodies and those benefits are clearly communicated to the mother, there is no mother who would refuse her child being tested and of course we are learning from the PMTC programs the key reason there has been wide acceptance and uptake of testing in the antenatal clinic among mothers, pregnant mothers, is because of the perceived benefits of preventing HIV to their unborn child so I wish the policy could come out very, very strongly to emphasize the benefits the child will get for being tested and then that benefits are clearly communicated to the mother. I personally believe that no mother would refuse the child to be tested.

**MALE SPEAKER:** Thank you Dennis. I think we will take the questions from the people who are standing, then we will have them answered in a group by the panel so that will then be in good time for the opening reception so the people who are standing, let's go to the other side, the extreme right, so that we come back to the middle.

**FEMALE SPEAKER:** Thank you very much for the presentation. My question is about repeat testing. We have had several mixed messages about coming back for repeat

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testing, so are we continuing with the traditional come back after three months or there are some modifications?

**MALE SPEAKER:** Next question. We are taking note of the questions.

Yes thank you, [Inaudible], pediatrician here in Rwanda [inaudible]. My question is about counseling. You were talking about counseling around testing but I would like to have your point of view about stopping test counseling as we are doing here just to be able to do a big scaling up of VCT.

**MALE SPEAKER:** Thank you for your question. The last one on the right.

**KATE HANKINS:** Yes, that was a great presentation Kevin. I just wanted to ask the question relating to the timing of [inaudible] developments. I am Kate Hankins from UNAIDS. When the 2004 policy came out, countries were already moving ahead. We had Botswana, Malawi, and in Kenya moving ahead with looking at alternative types of testing. We now have these reports from Uganda that are really exciting about home based testing and it seems to me that we should be looking at what are the key elements that are making this so successful and part of it is the [inaudible] obviously of prevention and care that is being offered but part of it is the community mobilization, the testing literacy, the fact that communities that want this are going to be first in line to get it and that

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we do need to move forward on normative guidance I think for this. These are not projects. These are programs in Uganda and I think countries need to know how to propose these and implement these in a way that will be effective.

**MALE SPEAKER:** Thank you very much. We have come to the middle here for the last two questions.

**NELSON JUANIKE:** Yes my name is Nelson Juanike. I would like to thank Dr. DeCock for the presentation. I was one of his medical students and so it gives me a lot of pleasure to ask this question. I am now in public health and I was waiting to hear what his presentation would say concerning what is happening on the ground. We are told that HIV testing should be voluntary, nobody should be, shouldn't be done to you against your will, but the reality on the ground is different. We have so many people having HIV testing done on them, either for studies, for promotions, for employment and I was hoping that there are some initiatives in dealing with this problem because to me it is one of the major problems that workers are facing worldwide, I mean in Africa at least.

**MALE SPEAKER:** Last question, thank you Juanike.

**VICTORIA:** Thank you very much. I am Victoria [inaudible] from [inaudible] Swaziland. I share the same sentiments with the previous speakers. Basically I appreciate in the presentation more especially because it is embracing

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health care providers who felt side lined in the previous traditional [inaudible] approach. The question that I have now that we feel we do have a breakthrough in HIV prevention, treatment, care and support is how best we can integrate the approach in low resource settings in lieu of human resource capacity and laboratory strengthening such that we maintain same day testing and increase result reception and also the second question I would like to ask is how best we can build on to existing practices like the [inaudible] program that was already on ground as a provider initiated approach to HIV testing? Thank you.

**MALE SPEAKER:** Thank you. I see a gentleman at the back with a burning, very last question.

**MALE SPEAKER:** Thank you very much. I now speak as a minister of health, being the minister from Guiana, and I remember in 2001 when countries like Guiana were talking about pursuing testing with these present guidelines, people were lukewarm, didn't provide support and so Guiana today feels vindicated. Those guidelines have been adopted, what were implemented in Guiana years ago and I know other countries have done so and so I want to totally endorse this strategy. We need to increase testing. We need to stop stigmatizing HIV because that is what we do by setting up all these barriers to testing and if I have 15 minutes I would say the same things

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the minister from Botswana said, in fact increased testing has led to reduced stigma in settings like Guiana so you know for those who say it can't be done, move out of the way! Let's get it done! [Applause]

**MALE SPEAKER:** Thank you very much, sir. We very appreciate that comment. I just want to summarize the questions that have come for my panelists so that they can pick them out. Dennis has made very passionate plea about offering the benefits of testing for children and I think that my panelists picked up very well. There is the question about counseling, the role of counseling. I didn't get it very well and I think the panelists will be able to respond to that. The issue about home based testing and how to expand the base because this is a problem really that is on the ground in other countries like Uganda and is not really a pilot, it's something that is happening and have to expand it particularly in other countries. Monique talked about work place testing and made me pretty jealous because I missed Kevin's class but I've been in his public health class and I have learned a lot, so work place testing and the role of this I think, Kevin, that question is directly for you. The sixth question was about how best to integrate testing in low resource settings with a constrained human resources and how this can be used to strengthen laboratory capacity. That is my understanding of that question

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and I think that one of the ministers from Guiana has said what is music to my ears because I am a firm believer in testing after having been in Kevin's public health class so the panelists, please.

**ELIZABETH MARAM:** Okay let me respond to the question about repeat testing and should people be told to come back in three months? It is important to remember that guidelines, that kind of counseling should always be based on not three months from today's test but three months and increasing people are saying even two months since the last risky exposure, so we don't want to just tell everyone who is negative to come back in three months, although that is happening, I see in many countries so we want to encourage people to come back only if they have had recent risky exposure or if they are continuing with risky behavior. Both the CDC guidelines and the WHO guidelines do encourage repeat testing every 6-12 months for people who continue to engage in risky behavior.

**KEVIN DECOCK, M.D.:** I'll very quickly go through the questions and perhaps Josh could just add as appropriate. The WHO guidance has a whole, there is lots in there that I didn't cover including actually discussions of stigma and discrimination but it also talks about testing of groups at high risk in concentrated epidemics and similarly advises that for people with potential repeated exposure, 6-12 months would

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be an appropriate period for retesting. As far as counseling in health care settings is concerned, the emphasis in the guidance is on providing adequate information so people can make an informed choice about whether to decline their test or not but counseling is reserved for the test result, indeed the way we understand counseling. To my ex-student and the question about mandatory testing, firstly I always knew he had a very bright future. [Laughter] This actually is a difficult question and it came up interestingly in the South African discussions. The fellow who made the pitch for mandatory testing asked an audience like this how many of you have health insurance and 80% of the room put up their hand and in South Africa they have all had a mandatory HIV test. There is no choice about it or you don't get your insurance and it is difficult for us to know how do we address that? It is not, we don't like it, we don't recommend it, but do you ignore it? Do you work again, do you try and undo it or do you take a pragmatic approach and say well, if this is going on then at least let's ensure that it meets the quality and standards of other forms of testing so that people get their test results, have appropriate access to services, adds confidentiality, etc, etc, but that is a long debate and I am not taking a position on it. Human resources and lab capacity, I mean at this meeting I hope there is very important discussions about

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approaches to human resources, task shifting, getting lower cadres of people into the system, remunerating them to do work that specialists or nurses or doctors don't have to do.

Similarly important discussions on lab capacity and I thank the minister from Guiana for his wise comments and his sharing his experience.

**MALE SPEAKER:** The only question left is basically what to do with pre-test counseling. I see people waving, you can't hear me maybe? The only question left is what to do with pre-test counseling, for provider initiated testing and counseling we propose pre-test information. We give rather detailed guidance on what should go in pre-test information and pre-test information could be offered on an individual basis. It could be offered as a group. There was somebody asking about what about pre-test information in mother to child transmission, do we continue that? I think yes and often there could be group information. It was the only thing I thought was not answered by the other panelists.

**MALE SPEAKER:** Thank you very much. I think we should give a round of applause to our expert panel. [Applause] And I think we should also give the excellent audience we have with us a round of applause for staying all this time [applause] and asking some of the most engaging and bright questions after a very long day. Thank you very much, ladies and gentlemen, for

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attending. If you want to meet the panel, they are still  
available for discussion and we go to the opening reception in  
[inaudible]. Thank you.

[END RECORDING]